REMARKS

Claims 1 through 10 and 28 through 30 remain pending in the application. Claims 1 and 3 are amended herein. Claims 19 through 27 are cancelled herein. New claims 28 through 30 are added herein. Reconsideration of the application is requested based on the foregoing amendment and the following remarks.

Rejections under 35 U.S.C. § 112:

Claims 1 through 10 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claim 1 has consequently been amended to make it more definite.

The Office Action asserts in paragraph 4 at page 2 that the phrase "capable of" is not a positive limitation and is thus indefinite, citing In re Hutchison, 69 U.S.P.Q. 138, for support. Hutchison, however, is inapposite because Hutchison deals with claims directed to *articles* of manufacture. "Each of them contains functional statements which may not be regarded as limiting the claims, they being article claims," ibid. Hutchison thus says only that functional language applied to *articles* of manufacture is not limiting.

Claim 1, in contrast, is a method claim. Hutchison says nothing about functional language in method claims not being limiting, let alone being indefinite. Furthermore, method claims are customarily drafted in terms of functions performed. The present claim 1, for example, recites "detecting particles," "sedimenting particles," etc.

Finally, even if we assume, arguendo, that the phrase "capable of" is not limiting, as asserted in the Office Action, that still would not mean it is *indefinite*. "Not limiting" is different than "indefinite". The phrase "capable of" is part of a functional definition of a functionally described component, the "binding agent". The phrase "capable of" is appropriate in the context of the present claims as defining the "binding agent". Note the

specification defines "binding agent" as having this capability as well. Claims 1 through 10 are thus submitted to be definite. Withdrawal of the rejection of claims 1 through 10 is earnestly solicited.

Rejections under 35 U.S.C. § 103:

Claims 1 through 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stocker, US 4,560,647. The rejection is traversed. Reconsideration of the rejection of claims 1 through 10 is requested.

Claim 1 recites, in pertinent part:

"sedimenting particles in a sample across the first slanted solid phase to concentrate the particles."

Stocker neither teaches, discloses, nor suggests sedimenting particles in a sample across a first slanted solid phase to concentrate the particles, as recited in claim 1. Stocker, rather, covers the *entire* conical or keel-like bottom region of a Microtiter plate with anti-immunoglobulin, as described at column 1, lines 65 through 68, and column 2, lines 16 through 18. Stocker, therefore, does not concentrate the particles at all before the particles contact the immunoglobulin binding component.

The Office Action acknowledges that Stocker shows no concentration or staining of particles, or the segmentation of microorganisms in paragraph 7 at page 4. The differences between the claimed invention and Stocker, however, are more profound than that. Stocker also neither teaches, discloses, nor suggests sedimenting particles in a sample across a first *slanted* solid phase to *concentrate* the particles, as discussed above.

The Office Action goes on to assert in paragraph 7 at page 4 that,

"it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use the method of Stocker to segment microorganisms and stain the

particles at some time during the analysis."

Simple knowledge or awareness of one or another of the *individual* elements of a combination on the part of persons of ordinary skill in the art at the time the invention was made, however, is not determinative of whether it would have been obvious to *combine* those elements. The test for obviousness under 35 U.S.C. § 103 (a), rather, as set forth by the United States Supreme Court in Graham v. John Deere, Co., 383 U.S. 1, 17-18 (1966), requires the scope and content of the prior art to be determined, the differences between the prior art and the claims at issue to be ascertained, and the level of ordinary skill in the pertinent art resolved.

Furthermore, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984). A suggestion, teaching or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." C.R. Bard, Inc. v. MP3 Sys., Inc., 157 F.3d 1340, 1352 (Fed. Cir. 1998). "When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references." In re Rouffet, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). NO MOTIVATION

Finally, the suggestion must be clear and particular; broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120 (Fed. Cir. 2000).

Here, the Office Action points to no evidence, either in the references or the general knowledge of the prior art, of a suggestion or motivation to modify Stocker by sedimenting particles in a sample across a first slanted solid phase to concentrate the particles, as recited in claim 1. The broad conclusory statement in the Office Action to the effect that

"it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use the method of Stocker to segment microorganisms and stain the particles at some time during the analysis" is not "evidence" of a suggestion or motivation to modify Stocker as required for a finding of obviousness.

Furthermore, even if Stocker were modified in the manner proposed in the Office Action, it would still not result in sedimenting particles in a sample across a first slanted solid phase to concentrate the particles, as recited in claim 1. Thus, modifying Stocker in the manner proposed by the Office Action would not produce the claimed invention.

The Office Action asserts further that,

"Since viral antigens or antiviral antibodies could be determined with the method of the reference, one could easily have used the virus particle itself with a reasonable expectation of success."

But even if the virus particle itself were used it would not amount to sedimenting particles in a sample across a first slanted solid phase to concentrate the particles, as recited in claim 1. Thus, modifying Stocker in the manner proposed by the Office Action would not produce the claimed invention.

The Office Action asserts further that,

"In addition, it would have been obvious to stain the particles before visualization, as this would allow for more efficient and accurate measurement of the amount of analyte presence."

But even if the particles were stained before visualization, it would not amount to sedimenting particles in a sample across a first slanted solid phase to concentrate the particles, as recited in claim 1. Thus, modifying Stocker in the manner proposed by the Office Action would not produce the claimed invention.

Finally, the Office Action asserts that,

"Further, it would have been obvious to concentrate the particles for analysis prior to conducting the binding assay, as this step would allow for greater binding efficiency."

But even if the particles were concentrated for analysis prior to conducting the binding assay, it would not amount to sedimenting particles in a sample across a first slanted solid phase to concentrate the particles, as recited in claim 1. Thus, modifying Stocker in the manner proposed by the Office Action would not produce the claimed invention.

Stocker, in fact, is working with red blood cells in a blood sample and therefore has no motivation to do any concentration at all. Note, e.g. that the "sediment" described in Stocker at column 2, line 1 refers to particles (e.g. red blood cells) that have already passed by the immobilized antibody and do not bind to them. This is quite different from forming a concentrated sediment before contacting and binding to an immobilized antibody, as recited in claim 1.

Furthermore, the vessel in Stocker has a conical or keel- shaped bottom with their binding moiety bound to the inside surfaces of the conical or keel-shaped bottom. The examples recite a V-shaped bottom wells in a Microtiter plate. The particles will strike only *one* of the inner surfaces of each well when sedimenting or centrifuging. A person observes binding or non-binding by looking at the well from above.

Claim 1, in contrast, recites sedimenting the particles across a first slanted solid phase followed by a second solid phase having the binding agent. Stocker lacks anything that resembles two different solid phases in a vessel/well. Stocker, rather, has a conical bottom, which simultaneously binds and only partially concentrates particles that do not bind. This is different from the claimed method which first concentrates particles for

subsequent binding at a later step.

Claim 1 recites further:

"sedimenting the particles across a second solid phase where the second solid phase contains at least one immobilized binding agent capable of binding to at least one particle in the sample."

Stocker neither teaches, discloses, nor suggests sedimenting particles across a second solid phase where the second solid phase contains at least one immobilized binding agent capable of binding to at least one particle in the sample, as recited in claim 1. Claim 1 is thus submitted to be allowable. Withdrawal of the rejection of claim 1 is earnestly solicited.

Claims 2 through 10 and 28 through 30 depend from claim 1 and add further distinguishing elements. Claims 2 through 10 and 28 through 30 are thus also submitted to be allowable.

Claims 3, in particular, recites,

"wherein different specific binding agents are immobilized on different regions on the solid phase."

Stocker neither teaches, discloses, nor suggests different specific binding agents, each one immobilized at a different region on the (second) solid phase, as recited in claim 3. Stocker, rather, coats the entire region with one binding agent.

Furthermore, Stocker neither teaches, discloses, nor suggests mixing the two binding agents together in the immobilizing region. Stocker provides no motivation to have each binding agent at a separate region. Indeed, Stocker is detecting concentration of particles into a central pellet or diffuse binding to their vessel wall. This would not be operable with plural binding agents because one could not determine which binding agent

is actually doing the binding. Claim 3 is thus submitted to be allowable. Withdrawal of the rejection of claims 2 through 10 is earnestly solicited.

Conclusion:

Accordingly, in view of the reasons given above, it is submitted that all claims 1 through 10 and 28 through 30 are allowable over the prior art. Since the rejections based on 35 U.S.C. § 112, second paragraph have been addressed , it is submitted that all of claims 1 through 10 and 28 through 30 are now allowable. Allowance of all claims 1 through 10 and 28 through 30 and of this entire application are therefore respectfully requested.

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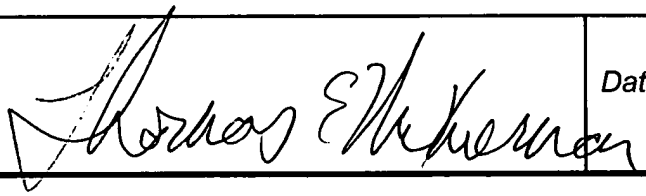
<tr><td>Siganture</td><td colspan="3">  </td><td>Date</td><td>19 JN 03</td></tr>
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